The multiparameter MLC-CFSE test to predict T cell-allo-immune reactivity in renal transplant recipients.

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To select T cell properties intrinsic to the transplant recipient, which can discriminate between patients who will likely experience acute cellular rejection episodes from those who don*t.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON29895

Source
ToetsingOnline

Brief title
Predictive value of multiparameter MLC-CFSE

Condition

- Other condition
- Immune disorders NEC
- Genitourinary tract disorders NEC

Synonym
rejection

Health condition

rejectie na niertransplantatie

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Nierstichting Nederland

Intervention

Keyword: alloreactivity, CFSE, renal transplant, T-cell

Outcome measures

Primary outcome

We expect to find a combination of read out paramters, measured in one assay ,

which before transplantation can discriminate between patients at risk for

acute cellular rejection and patients who are not.

Secondary outcome

Not apllicable

Study description

Background summary

Despite the essential role for T cells in the pathogenesis of acute allograft rejection, as yet no clinical useful method to measure pre-existing allospecific T cell immunity exists.
If such could be measured in a reliable way, tailor made immunosuppressive drug therapy could finally become practice. Considering increasing morbidity due to infections complicating the immunosuppressive state, a test to predict T cell alloreactivity after transplantation would be a major step forward in management of the renal transplant patient.
We now have much experience with the multiparameter MLC-CFSE-assay, which enables to determine a combination of quantitative and qualitatieve properties of alloreactive T cells in one assay. Preliminary data indicate that this test is able to predict the posttranplant clinical course.

Study objective

To select T cell properties intrinsic to the transplant recipient, which can discriminate between patients who will likely experience acute cellular rejection episodes from those who don*t.

Study design

A retrospective study is currently being done to select parameters that discriminate between patients with or without acute cellular rejection. These parameters will be used during the prospective study.
The findings will be validated in a patientcohort that shifts at 6 months post-transplantation from triple to double immunosuppressive drug treatment, as part of current standard treatment.
This enables us to also evaluate the power of this test to predict alloreactivity after diminution of immunosuppressive drug therapy.

Study burden and risks

For the analysis during this study, 3X42ml blood is needed. 42ml blood pre-transplant, 42ml blood 6-month post-transplant and 42ml blood 12-month post-transplant.
According to our experience the risk and burden are minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Renal transplant recipients of a first or second graft,.

Exclusion criteria

Highly immunized paitents with panel reactive antibodies >85% will be excluded

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2006
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL12588.018.06